

K112744

OCT 20 2011

Bard Access Systems, Inc.  
 Sapiens\* Tip Confirmation System (TCS)  
 Special 510(k) Premarket Notification

### 510(k) Summary 21 CFR 807.92

#### Sapiens\* Tip Confirmation System

<b>General Provisions</b>	Submitter Name:	Bard Access Systems, Inc.
	Submitter Address:	605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Henry Boland Regulatory Affairs Specialist henry.boland@crbard.com 801.522.5000 ext. 5428 801.522.5425 fax
	Date of Preparation:	20 September 2011
<b>Subject Device</b>	Trade Name:	<b>Sapiens* Tip Confirmation System</b>
	Classification Name:	21 CFR 880.5970 - Class II LJS - Accessory to percutaneous, implanted, long-term intravascular catheter
<b>Predicate Device</b>	Trade Name:	<b>Sapiens* Tip Confirmation System</b>
	Classification Name:	21 CFR 880.5970 - Class II LJS - Accessory to percutaneous, implanted, long-term Intravascular catheters
	Premarket Notification:	K093775, concurrence date 15 July 2010
	Manufacturer:	Bard Access Systems, Inc.
<b>Device Description</b>	<p>The <b>Sapiens*</b> TCS consists of the following elements: PC netbook running <b>Sapiens*</b> TCS software, <b>Sapiens*</b> TCS ECG module, ECG leads connection, printer (optional), and remote control (optional). A stylet inserted into a central venous catheter can be connected to the <b>Sapiens*</b> TCS system via the <b>Sapiens*</b> TCS ECG leads connection, establishing a direct electrical connection to the catheter distal tip for ECG signal measurement. When the central venous catheter stylet is connected to <b>Sapiens*</b> TCS, the <b>Sapiens*</b> TCS PC netbook displays a cardiac electrical signal from the four ECG electrodes, including the catheter stylet (intravascular electrode) and three body electrodes, which provide ECG waveforms. The intravascular ECG waveforms provided by the <b>Sapiens*</b> TCS can be used for guiding and positioning of the central venous catheter. These ECG waveforms can be printed using an optional printer to document the procedural record for the patient's file.</p>	

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**Indications for Use / Intended Use** The **Sapiens\*** Tip Confirmation System (TCS) is indicated for guidance and positioning of Peripherally Inserted Central Catheters (PICCs). The **Sapiens\*** TCS provides real-time PICC tip location information by using the patient's cardiac electrical activity. **Sapiens\*** TCS is indicated for use as an alternative method to chest X-ray and fluoroscopy for PICC tip placement confirmation in adult patients.

Limiting but not contraindicated situations for this technique are in patients where alterations of cardiac rhythm change the presentation of the P wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythm. In such patients, who are easily identifiable prior to PICC insertion, the use of an additional method is required to confirm catheter tip location.

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**Technological Characteristics** Technological characteristics of the subject **Sapiens\*** TCS are equivalent with respect to the basic system design and function to that of the predicate device. Differences do not raise any new questions regarding safety and effectiveness.

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**Safety & Performance Tests** Verification and validation activities were designed and performed to demonstrate that the subject **Sapiens\*** TCS met predetermined performance specifications. The following standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device:

IEC 60601-1:1988/1991/1995 Medical Electrical Equipment – Part 1: General Requirements for Safety

IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

The subject device met all pre-determined acceptance criteria and demonstrated substantial equivalence as compared to the predicate device.

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**Summary of Substantial Equivalence** Based on the indications for use, technological characteristics, and safety and performance testing, the subject **Sapiens\*** TCS, met the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, materials, principles of operation and indications for use to the predicate **Sapiens\*** TCS.

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\* Sapiens is the trademark and/or registered trademark of C.R. Bard, Inc. or an affiliate.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Mr. Henry Boland  
Regulatory Affairs Specialist  
C.R. Bard, Inc.  
Bard Access Systems  
605 North 5600 West  
Salt Lake City, Utah 84116

OCT 20 2011

Re: K112744  
Trade/Device Name: Sapiens Tip Confirmation System  
Regulation Number: 21 CFR 880.5970  
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter  
Regulatory Class: II  
Product Code: LJS  
Dated: September 20, 2011  
Received: September 21, 2011

Dear Mr. Boland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

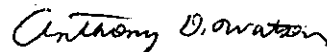
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.  
Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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Sapiens\* Tip Confirmation System (TCS)  
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### Indications for Use Statement

510(k) Number (if known): K112744

Device Name: Sapiens™ Tip Confirmation System

Indications for Use:

The **Sapiens\*** Tip Confirmation System (TCS) is indicated for guidance and positioning of Peripherally Inserted Central Catheters (PICCs). The **Sapiens\*** TCS provides real-time PICO tip location information by using the patient's cardiac electrical activity. **Sapiens\*** TCS is indicated for use as an alternative method to chest X-ray and fluoroscopy for PICO tip placement confirmation in adult patients.

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Prescription Use   X   AND/OR Over-The-Counter Use             
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)  
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony V. Smith  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K112744